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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,191	07/16/2002	Anand Achanta	C75103	1515

20462 7590 03/11/2004

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,191	ACHANTA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-103 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-103 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment and Response to Notice of File Missing Part filed 07/16/02, and Information Disclosure Statement filed 03/14/02.

Claims Objection

Claims 28 and 30-34 are objected to because of the following informalities:

The term "chlorpheneramine" or chloropheneramine" should read "chlorpheniramine". Appropriate correction is required.

The term "phenylpeopanolamine" in claim 33 should read "phenylpropanolamine".

Claim 58 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 38. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 59 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 39. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected in the use of the abbreviation "PPA". What is PPA? Full spelling of the term "phenylpropanolamine (PPA)" is suggested when the term is first appear in the independent claims.

Claim 11 is rejected in the use of the term "CPM". What is CPM?

Claim 21 is rejected in the use of the term "PPM". What is PPM?

Claim 41 is rejected in the use of the term "PSE".

Claim 30 is rejected in the use of the limitation "a beadlet of chlorpheneramine maleate" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim, because claim 24 does not recite chlorpheniramine.

Claim 31 is rejected in the use of the limitation "a beadlet of phenylpropanolamine" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 is rejected in the use of the limitation "wherein the amount of chlorophen eramine maleate" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 is rejected in the use of the limitation "wherein the amount of phenopeopanolamine" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 54 is rejected in the use of the limitation "a beadlet of pseudoephedrine" in line 2. There is insufficient antecedent basis for this limitation in the claim, because claim 24 does not recite beadlet of pseudoephedrine.

Claim 67 is rejected for failing to further limit the subject matter of claim 62. It is suggested the use of the phrase "further comprising".

Claim 93 is rejected in the use of the limitation "wherein the amount of dextromethorphan" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, 11-13, 15-17, 21-31, 38, 58 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Oshlack et al. US 5,472,712.

Oshlack discloses a stabilized solid controlled release formulation comprising substrate, such as beads (beadlet), pellets, or spheroids of active agents being coated with aqueous dispersion of hydrophobic polymer to obtain a weight gain of from about 2

to about 25% (abstract and column 6, lines 20-42). The aqueous dispersion of hydrophobic polymer is a dispersion of ethyl cellulose, such as Aquacoat® or Surelease® (column 8, lines 47-66, and examples). The substrate coated with active agents can be protected with a barrier coating of hydroxypropylmethyl cellulose (HPMC) (column 9, lines 32-67). The active agents can be selected from therapeutically active agents, including chlorpheniramine and phenylpropanolamine (column 14, lines 13-33). The formulation further comprises an additional dose of active agent in an overcoating coated on the outer surface of the controlled release coating (immediate release coating) (column 16, lines 64 through column 17, lines 1-6).

The examiner notes that the cited reference does not teach the glass transition point of the ethyl cellulose dispersion. However, it is the examiner's position that the particular glass transition temperature is inherent because the reference teaches the use of the claimed ethyl cellulose dispersion, namely, Surelease®.

Claims 1-9, 11-19, 21, 22, 24-28, 30-33, 41-49, 51, 53-55, 61-67, 71-74, 78, 93 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Paradissis US 5,133,974.

Paradissis discloses a sustained release formulation comprising from 0-50% of an immediate release particle containing core of at least one drug and up to 100% of an extended release particle which contains the immediate release particle coated with a dissolution modifying system and optionally additional drug (column 3, lines 62-68). The core containing from about 4 to about 85% of drug selected from pseudoephedrine

HCl, chlorpheniramine maleate, dextromethorphan and phenylpropanolamine (abstract, column 4, lines 60-66, column 5, lines 8-11, and claims 1, 2, 18-20, and 29). The active core is being coated with from about 2 to about 35% of dissolution modifying system coating containing ethyl cellulose (column 6, lines 19-27). The coated particles can then tabletted or filled in gelatin capsules (column 9, lines 9-24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. US 5,133,974, in view of Adusumilli et al. US 5,595,758.

Paradissis is relied upon for the reason stated above. Paradissis does not teach combination of drug as claimed in claims 74-77.

Adusumilli teaches gelatin capsule comprising combination of immediate release and sustained release drug particles selected from analgesic/decongestant, antihistamine/decongestant, decongestant/anti-tussive, decongestant/anti-tussive/antihistamine, and the like (column 5, lines 62 through column 7, lines 1-2). Thus, it would have been obvious for one of ordinary skill in the art to modify the sustained release formulation of Paradissis using the combination of drugs in view of the teaching of Adusumilli with the motivation of providing an oral dosage containing

sustained release and immediate release of combination of drugs useful for the treatment of cold and sinus.

Claims 1, 10, 11, 20, 25, 39, 41, 50, 59, 68-70, and 80-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. US 5,472,712, in view of Sparks et al. US 4,940,588.

Oshlack is relied upon for the reason stated above. Oshlack does not teach polyvinyl alcohol as a seal coat. However, Oshlack teaches any film-former known in the art may be used in a barrier protected coating layer (column 9, lines 61-63).

Sparks teaches discrete micro-particle having average size of from 0.1 to 125 μm is being coated with film-forming polymer such as polyvinyl alcohol (column 3, lines 1-62). Thus, it would have been obvious for one of ordinary skill in the art to modify the sustained release formulation of Oshlack using polyvinyl alcohol in a barrier coating because Sparks teaches polyvinyl alcohol is a known film-forming polymer. The expected result would be a sustained release dosage form suitable for administering phenylpropanolamine, dextromethorphan, pseudoephedrine, and the like.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fuisz et al., Ambergaonkar et al., and Mehta et al. are cited as being of interest for the teachings of controlled release dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600